UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

UNITED STATES OF AMERICA, et al., Plaintiffs, v. DON J. WAGONER, et al., Defendants.	CASE NO. 2:17-CV-478-HAB

OPINION AND ORDER

This lawsuit was initiated by the United States of America and the State of Indiana (together, "Plaintiffs" or "the Government") in 2017, alleging that Defendants Don Wagoner and Wagoner Medical Center, L.L.C. ("Defendants") engaged in false and fraudulent billing for medical services to Indiana Medicaid by miscoding thousands of claims involving a single type of urine drug screen test. Eight years later—after a slew of amended complaints, multiple dispositive motions, and on the eve of trial—tensions are clearly no less heated than they were at the start of litigation.

Now before the Court are Defendants' motions to exclude the expert testimony and reports of Lori Endicott, RN, CCM, CPC, COC; Timothy E. King, M.D.; and Ann D. Zerr, M.D. (ECF Nos. 210, 211). In the first motion, Defendants argue the reports and testimony of Ms. Endicott and Dr. King regarding proper coding practices should be excluded for insufficient qualifications and a lack of recognized methodology. (ECF No. 210). In the second, Defendants claim Ms. Endicott, Dr. King, and Dr. Zerr all lack the qualifications to testify regarding the chemical methodology of the urine drug screens utilized by the Defendants, and that any testimony by these three on the subject would be unreliable and confusing to the jury. (ECF No. 211). These motions

have been fully briefed (ECF Nos. 212, 214, 218, 219), making them ripe for ruling. The Court will address each motion and each expert in turn.

For the reasons below, the Court DENIES Defendants' Motion to Exclude Testimony Regarding Coding (ECF No. 210) and DENIES Defendants' Motion to Exclude Testimony Regarding Chromatography (ECF No. 211).

I. Introduction

A. Factual and Procedural Background

The Court presumes familiarity with the facts and procedural history underlying this case, which have been set forth in previous orders—*see* ECF Nos. 153, 159, 184—but will briefly summarize them here.

This lawsuit stems from the Defendants Don Wagoner, M.D., and Wagoner Medical Center, LLC's presentation of around 5,217 claims to Indiana Medicaid for the testing of urine samples of their pain medication patients with drug screening testing kits. From January 1, 2011 through January 13, 2013, the Defendants sought reimbursement from Indiana Medicaid for processing these thousands of claims, and the Government contends the Defendants billed and received payment from Indiana Medicaid for the tests up to a dozen times per test, using the same Current Procedural Terminology ("CPT") code for each test, resulting in an overpayment of approximately $1,030,162.03. It is undisputed that Defendants used the same type of urine drug test for every claim during this time frame and that every claim was coded as CPT Code 80101, sometimes with a 91 modifier.

At the heart of this case are the urine drug screening test kits and how they should be properly coded when billing the government for reimbursement. The Defendants performed the tests at issue with immunoassay multiplexed drug screening kits manufactured by Wondfo—

essentially a dip-stick urine test that can identify multiple drug classes. All parties agree that the American Medical Association ("AMA") is the authority on CPT codes and their proper use, as expressed in the AMA's CPT Code/Coding and CPT Assistant books.

The 2011 AMA codebook outlined several codes for billing urine drug tests, providing as relevant:

- 80100 – Drug screen, qualitative; multiple drug classes, chromatographic method, each procedure
- 80101 – Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class
    - (For qualitative analysis by multiplexed screening kit for multiple drugs or drug classes, use 80104)
- 80104 – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

See ECF No. 179-20, at 4 (parenthetical in original). The Government asserts the Wondfo tests should have been coded as 80104 because the tests did not use a chromatographic method.

Plaintiffs—the United States of America and the State of Indiana—initiated this suit in 2017 alleging multiple state and federal claims. Specifically, the United States of America brought three claims under the False Claims Act, 31 U.S.C. §§ 3729–33, based on Defendants presentation of the thousands of false claims to Indiana Medicaid (Count 1), Defendants presentation of false records or statements to Indiana Medicaid (Count 2), and the overpayment caused by the submission of the false claims (Count 3). Together, the federal and state governments brought joint claims under common law for payment by mistake (Count 4) and unjust enrichment (Count 5). Finally, the State of Indiana brought three claims under the Indiana Medicaid False Claims Act for presentation of false claims (Count 6), false statements material to false claims (Count 7), and false statements material to an obligation to pay money (Count 8). Also under Indiana law, the State

brought claims for improper receipt of Medicaid payments (Count 9) and for being a victim of a property crime (Count 10). (ECF No. 83, Government's Third Amended Complaint).

Discovery began in December 2018, and discovery deadlines were extended several times throughout the following years. Most recently, the Court granted in part and denied in part Defendants' motion for summary judgment, granting summary judgment in favor of the Defendants on the Government's claims in Counts 1 and 2 that are based on a lack of medical necessity, and denying summary judgment on the Government's claims in Counts 1 and 2 that are based on Defendants' use of CPT Code 80101 and on damages. (ECF No. 184). The Defendants did not move for summary judgment on the Government's claims in Counts 1 and 2 stemming from the Defendants' use of Modifier 91 or for Counts 3–10, meaning those claims remain issues for trial.

B. Experts

Three of the Government's experts are at issue in these motions: Lori Endicott, RN, CCM, CPC, COC; Timothy E. King, M.D.; and Ann D. Zerr, M.D.

i. Lori Endicott

Lori Endicott is a Registered Nurse, Certified Case Manager, Certified Professional Coder, and Certified Outpatient Coder. Ms. Endicott has been a licensed nurse since 1994, and since 2014 she has been credentialed through the American Academy of Professional Coders ("AAPC") as a certified professional coder. (ECF No. 218-1, at 1). Ms. Endicott furnished her expert report in February 2022 and provided that she was asked to provide her expert opinions regarding (1) "the correct CPT coding (Current Procedural Terminology) for the One Step Multi-Drug Urine Test Panel as utilized and billed by Dr. Wagoner and the Wagoner Medical Clinic, LLC during the timeframe of 2011-2013," and (2) the reasonableness of the opinions stated in the Defendant's

expert report by Christine Miller. (*Id.*). As part of her report, she reviewed multiple CPT coding materials from the American Medical Association and the AAPC, including the 2011 AMA CPT Coding book and CPT Assistants from 1993 and 2010, Provider Bulletins from the Indiana Health Coverage Programs, the package insert and materials from the urine drug screening kit utilized by Defendants, expert reports from both Defendants' expert Ms. Miller and Plaintiffs' expert Dr. King, as well as transcripts of depositions from multiple witnesses. (*Id.* at 3). Ms. Endicott testified that she reviewed all the material provided, and, using those materials as well as her coding expertise, came to the following conclusions:

- CPT Code 80104 is the correct code for urine drug screens (UDS) performed by WMC when using the multiplex screening kit testing as represented by the One Step Multi-Drug Urine TEST Panel (UDS kit).

- CPT code 80104 was allowed to be billed only once per day, when performed using the One Step Multi-Drug Urine Test Panel (UDS kit).

- Dr. King's report is the correct interpretation of CPT codes for urine drug screens. He correctly identifies that the UDS kit used by WMC, "One Step Multi-Drug Urine Test Panel" is not a chromatographic method of testing for drugs in the urine but is instead an immunoassay method.

- In no circumstances on/after January 1, 2011, was WMC allowed to bill 80101 when performing urine drug screens using this UDS kit.

- The use of Modifier 91 by WMC was inappropriate.

- In the defense's expert report . . . , Ms. Christine Miller's narrative review *incorrectly* identifies 80101 as the procedure code to bill for performing the drug screen testing using UDS kit. The report does not provide evidence-based support using CPT instructions and guidelines why CPT 80101 would have been correct nor why appending modifier 91 would have been appropriate.

- There was ample, available publicized guidance that should have warned WMC away from billing these UDS kits as 80101 and as 80101 as multiple units after January 1, 2011.

(*Id.*; ECF No. 223-2).

ii. Dr. Timothy King

Dr. Timothy King has been a practicing physician since graduating from the Indiana University School of Medicine with his MD in 1975. Prior to his MD, he received a Bachelor of Arts in Chemistry from Indiana University in 1970, and has since authored or co-authored numerous papers highlighting his original research in chemistry and biophysics. (ECF No. 70-3, at 2). Since 1992, he has specialized in treating chronic pain patients, including serving as the Founder and Chief Medical Officer for Advanced Pain and Anesthesia Consultants PC. (*Id.* at 7).

Dr. King issued his expert report in June 2019. In that report, he states that he was asked to render an opinion "as to proper CPT 2011 coding for the *One Step Multi-Drug Urine Test Panel* (multiplex screening kit) as utilized and billed by Dr. Wagoner and the Wagoner Medical Clinic, LLC." (ECF No. 209-4). To form his opinion, Dr. King asserted he reviewed the Amended Complaint, the 2011 CPT Coding book and CPT Assistants from 1994 and 2010, an Indiana Healthcare Provider ("IHCP") Bulletin from March 2009, as well as the package insert and materials from the urine drug screening kit used by Defendants. Based on his review of the materials, combined with the his experience and knowledge as a practicing physician and chemistry researcher, Dr. King reported his opinion that Code 80104 was the proper code for this type of test kit, that the test kit utilizes "a competitive binding immunoassay methodology analogous to that used for dip stick pregnancy testing" and thus the kit "does not use chromatographic methodology to determine the presence or absence of drugs." (*Id.* at 2). His report also outlines the difference between the test used by Defendants—a dip-stick rapid test—and a test that would qualify as a chromatographic method test, and his belief that a "physician with ordinary competence would understand the CPT Manual's instructions to use code 80104 for qualitative analysis" when using a test kit such as the one used by Defendants. (*Id.* at 4).

Based on his review of the materials, combined with his own knowledge and expertise, Dr. King concluded that the Defendants applied the incorrect code for the drug testing kit. (*Id.* at 5).

iii. Dr. Ann Zerr

Dr. Ann Zerr is also a practicing physician, having received her M.D. from the University of Missouri School of Medicine in 1985 and completing a residency in Internal Medicine at the Medical College of Virginia. (ECF No. 223-3, at 207). She is a well-respected physician and has received numerous awards in recognition of her medical proficiency. (*Id.*). In addition to her medical practice, she has served as an Associate Professor of Clinical Medicine at the Indiana University School of Medicine since 1996. (*Id.*).

In their second *Daubert* Motion, the Defendants challenge whether Dr. Zerr is qualified to render an opinion on chromatography. Dr. Zerr serves as a Fed. R. Civ. P. 26(a)(2)(C) expert and thus has not rendered an expert report. She has, however, offered deposition testimony and was the signatory verifying the State of Indiana's Answers to the Defendants' Interrogatories, both of which include her relevant expert conclusions. According to Dr. Zerr's testimony, she reviewed the AMA CPT materials, multiple IHCP bulletins, the Wondfo test kit package materials, and previous deposition testimony for this case, including the depositions of Dr. King and Lynnette Griffis.

By signing off on the State's response to the request for interrogatories, Dr. Zerr adopted the conclusions therein as her own. As relevant here, those conclusions included (1) accepting the definition of "chromatography" as defined by the AMA CPT guidance; (2) explaining that chromatographic testing requires expensive equipment to do the work described in that definition; (3) based on the AMA's definition, the test kit used by the Defendants did not use a chromatographic method; and (4) because the test kit was a multiplexed screening kit using a

testing method that was not chromatographic, the appropriate CPT Code was CPT Code 80104, not 80101 as submitted by Defendants. (*Id.* at 225–31).

In her deposition, Dr. Zerr testified much the same. Dr. Zerr recounted her preparation for responding to the interrogatories and confirmed that she formed her answer about chromatography by using her science training as a physician as well as her review of the AMA CPT materials. (*Id.* at 64, 151). Generally, she described chromatography as being an inherently complex testing method, requiring specific chromatography equipment and "significant expertise interpreting tests." (*Id.* at 69). She described her understanding of chromatography—and the difference between a chromatographic testing method as opposed to a non-chromatographic method—as "taking a substance and separating it . . . the textbook example is a – and that different chemicals separate out differently. And so either it could do a gas, it could do it as colors on a spectrum, but a urine drug test done in a physician's office is present or not present and chromatography is not like that. Chromatography is – it is a line that different substances come out differently. . . . A simple test, an immunoassay, is yes or no." (*Id.* at 66–67). Based on her review of the AMA CPT guidance and the Wondfo test kit materials, Dr. Zerr testified that she believed the test kit—though it stated it is a chromatographic absorbent device—was not describing a chromatographic method but instead describing that the dip-stick changed colors to indicate the presence of certain drugs. (*Id.* at 90 ("I think the answer is in the antibody dye conjugate binding site. So that says that the antibody – as the urine is exposed to the test strip, it turns a color, and I think that's what they're referring to because they clearly say that it's a competititve immunoassay, which is not chromatography.")). Ultimately, based on her review of the materials, Dr. Zerr came to the conclusion that this is a multiplexed immunoassay test that did not use a chromatographic method,

and following CPT guidance, a multiplexed screening kit should have been coded as CPT Code 80104, not 80101. (*Id.* at 154).

II. Legal Standard

Federal Rule of Evidence 702 and the Supreme Court's opinion in *Daubert* governs the admissibility of expert testimony. *Daubert*, 509 U.S. 579; *see also Lees v. Carthage*, 714 F.3d 516, 521 (7th Cir. 2013) (explaining that Rule 702 has superseded *Daubert*, but that its standard of review still applies). Rule 702 and *Daubert* require the district court to engage in a three-part analysis. *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). The Court must determine "whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* Experts can be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702.

"The purpose of [the *Daubert*] inquiry is to vet the proposed testimony under Rule 702's requirements that it be 'based on sufficient facts or data,' use 'reliable principles and methods,' and 'reliably appl[y] the principles and methods to the facts of the case.'" *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 804 (7th Cir. 2012) (quoting Fed. R. Evid. 702). Whether to admit the expert testimony lies within the discretion of the district court. See *Lapsley*, 689 F.3d at 810 ("[W]e 'give the district court wide latitude in performing its gate-keeping function and determining both how to measure the reliability of expert testimony and whether the testimony itself is reliable.'") (quoting *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 894 (7th Cir. 2011)). "[T]he party seeking to introduce the expert witness testimony bears the burden of demonstrating that the expert witness testimony satisfies the [*Daubert*] standard by a preponderance of the evidence." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 784 (7th Cir. 2017).

Relevant here, where a party's challenges to the proposed expert testimony "do not go to admissibility but to the appropriate weight that should be accorded to the evidence[,] '[d]etermination on admissibility should not supplant the adversarial process; shaky expert testimony may be admissible, assailable by its opponents through cross-examination.'" *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010) (quoting *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir.2010)).

III. Discussion

A. Coding Experts

The Government has proffered two expert witnesses—Lori Endicott and Dr. Timothy King—to provide testimony regarding the correct Current Procedural Terminology ("CPT") billing code that they believe Defendants should have used to bill Indiana Medicaid for the type of urine drug test kit Defendants used during the relevant timeframe. Both Ms. Endicott and Dr. King used their experiences—Ms. Endicott as a certified professional coder, Dr. King as a physician responsible for coding his services—as well as the American Medical Association's CPT guidance and the package materials from the urine drug test kit to come to the conclusion that the kit should have been coded as CPT Code 80104 and that Defendants incorrectly coded the kit as CPT Code 80101. (ECF No. 209-4, King Report; ECF No. 218-1, Endicott Report).

Defendants lob a flurry of arguments and accusations in their motion, but those ultimately funnel down to two objections: qualifications and methodology. As to the first, Defendants concede Ms. Endicott—a longtime Certified Professional Coder with the American Academy of Professional Coders ("AAPC") as well as an experienced Registered Nurse—is qualified to testify about proper CPT coding. Defendants object to Dr. King's qualifications, however, considering he has no accreditations or certifications in coding, has never served or been recognized as an

expert in the field of medical coding, and he testified that "while he may *recommend* a CPT code to be billed, he has never actually submitted a claim form to an insurance payor, himself, without first having a billing company that employs certified coders review his recommended code." (ECF No. 210, at 19). As to methodology, Defendants make the same argument for both experts: the proffered opinions are unreliable because they did not review patient medical records related to individual claims as purportedly required by the retrospective audit procedures of the AAPC.

The Court will first address Dr. King's qualifications before turning to the Defendant's methodology argument.

i. Dr. King is qualified to testify on proper medical coding

Defendants claim Dr. King is not qualified to testify as an expert in the area of medical coding because he has no certifications or accreditations in coding, he has never previously served as an expert in the field of medical coding, and he does not submit CPT billing codes in his own practice, but merely recommends them to a different team of certified coders who then submit the claims.

The Government contends that, while Dr. King is not a certified professional coder, his decades of experience as a physician and extensive education in research make him eminently qualified to testify about the type of urine drug test Defendants used, the chemistry the drug test employs, and the CPT codes under which the drug test should be billed, because physicians are ultimately responsible for what they bill. Citing *Smith v. Ford Motor Co.*, 215 F.3d 713 (7th Cir. 2000), the Government argues the Seventh Circuit held that district courts should allow expert testimony that is helpful, even if the experts do not have the precise credentials asked for by the opposing party. Although Dr. King does not have certifications as a professional coder, as an experienced physician treating the same type of chronic-pain patients as Defendants, and as a

physician responsible for suggesting the proper CPT codes for administered tests, the Government asserts Dr. King is qualified to render an opinion on how this one urine drug test should be properly coded.

In reply, Defendants make much to do about the fact that Dr. King does not submit his own billing codes, but instead relies on a third party of certified coding professionals to "vet[ ] the coding for his services." (ECF No. 218, at 13). Defendants also present, for the first time in their reply brief, a new argument for why Dr. King's opinion and testimony should be excluded—his testimony would present an opinion of what the Defendants' beliefs objectively should have been regarding drug coding, and that opinion would be irrelevant to the subjective scienter requirement for an FCA claim and ultimately confusing to the jury.

Under the Federal Rules of Evidence, a person may qualify as an expert through "knowledge, skill, experience, training or education." Fed. R. Evid. 702. Notably, although "extensive academic and practical expertise" may sufficiently qualify a potential witness as an expert, *Bryant v. City of Chi.*, 200 F.3d 1092, 1098 (7th Cir. 2000), "Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience," *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 591 (7th Cir. 2000). *See also Smith*, 215 F.3d at 718 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). "Whether a witness is qualified as an expert can only be determined by comparing the area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) (internal quotation marks omitted). "The question . . . is not whether an expert witness is qualified in general, but whether his qualifications provide a foundation for him to answer a specific question." *Id.* at 617.

The Court finds Dr. King is qualified as an expert to testify as to his opinion regarding the correct CPT code to bill for the urine drug test kits used by the Defendants. Dr. King received his undergraduate degree in Chemistry from Indiana University in 1970 before pursuing a combined MD/PhD from the Indiana University School of Medicine. (ECF No. 211-12). After graduating with his MD in 1975, Dr. King pursued an anesthesiology residency at the University of Washington, making the choice to not complete his PhD. Though he has practiced as a physician since completing medical school, he has specialized since 1992 in treating patients complaining of chronic pain. From 1999-2014 he was the Founder and Chief Medical Officer of Advanced Pain and Anesthesia Consultants. (*Id.*) Dr. King testified multiple times throughout his deposition that, as a practicing physician, he was responsible not just for patient care but for the medical coding and billing as well. *See* ECF No. 223-1, King Dep. 41:25–42:5 ("[I]t's inherent that we as providers understand the coding, because in the end, when . . . the medical bill is submitted, the provider attests to the accuracy of the diagnosis code. So we do have to be familiar with it, and it is an inherent part of our day-to-day practice."); *id.* at 63:19–24 ("[T]he ultimate coding is . . . the responsibility of the provider, therefore, as part of a routine medical practice, the provider has to assume responsibility and note what would be the appropriate codes for the encounter or for the tests ordered."). Beyond his own responsibility for understanding billing and coding for his own patients, Dr. King testified that as Chief Medical Officer it was also his responsibility to educate individual providers about their responsibility for appropriate coding and that while APAC might enlist third-party certified coders for feedback and as a check for correct documentation, "in the end, the generally expected medical practice over the last couple decades has required that a physician be responsible for all his actions, including medical, legal, and billing." *Id.* at 68:25 – 69:9. Thus, Dr. King testified that not only has he ultimately been responsible for coding his own

medical services for over three decades, but he also has been responsible for teaching other physicians in his practice how to appropriately code. Though he may not be certified or accredited by any coding organizations, Dr. King's testimony as to his experience as a physician responsible for coding his services shows he is qualified to testify as a coding expert, specifically to give his opinion on how this type of urine drug test should have been coded by Defendants. *See Smith*, 215 F.3d at 718.

Defendants' focus on Dr. King's lack of certifications and his testimony that a third-party coding professional ultimately submits his billing for him is unpersuasive. As with Defendants' previous briefings in this case, the arguments are unsupported by pertinent authority, with very few citations to case law. And what case law is cited is only included for high level evidentiary principles, rather than support for any of the positions for which the Defendants would like the Court to rule in their favor. Whether or not Dr. King submits his own billing or merely recommends a code and then a third party submits his billing for him, he still testified that the physician takes the ultimate responsibility for coding. As a long-term practicing physician with a specific background in chemistry, Dr. King is qualified to testify as to how a reasonable physician would code the urine drug tests used here. The fact that Dr. King does not submit his own billing claims and instead relies on an outside expert to vet his billing for him simply goes to the weight of his testimony, not its admissibility, and is a topic that can be explored by Defendants through cross-examination. *See Metavante Corp.*, 619 F.3d at 760.

Regarding Defendants' argument that Dr. King's testimony would confuse the jury because an FCA claim is based on a subjective rather than objective state-of-mind, the Court finds this argument is waived because it was raised for the first time in a reply brief, leaving no chance for the Plaintiffs to respond. *See White v. United States*, 8 F.4th 547, 552 (7th Cir. 2021). But even if

this argument were not waived, Defendants included no legal authority that requires excluding an otherwise admissible expert opinion because the state-of-mind to which the expert is testifying is different from the underlying claim's scienter requirement. *See id.* ("[T]his court has repeatedly and consistently held that perfunctory and undeveloped arguments, as well as arguments that are unsupported by pertinent authority, are waived."); *see also Bank of Am., N.A. v. Veluchamy*, 643 F.3d 185, 190 (7th Cir. 2011) (quoting *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990)) ("It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work, create the ossature for the argument, and put flesh on its bones."); *White Eagle Coop. Ass'n v. Conner,* 553 F.3d 467, 476 n. 6 (7th Cir. 2009) ("[I]t is not the province of the courts to complete litigants' thoughts for them . . . ."). Further, in a case where a defense might be that the physician who submitted the claims "didn't know" those claims were improperly coded, evidence of what an objectively reasonable physician submitting similar claims would do is particularly relevant to the ultimate determination of liability. As such, the Court finds Defendants' relevance argument as to Dr. King's testimony waived. Defendants may renew any relevance objection at the time the evidence is introduced, but for now this objection goes to the weight of the evidence—a province for the jury—and not the evidence's admissibility.

ii. Ms. Endicott and Dr. King employed a methodology reliable for the scope of the opinion for which they were retained.

The crux of Defendants' first motion is their belief that Ms. Endicott and Dr. King employed deficient methodology in forming their opinions, and for that reason their testimony about proper medical coding should be excluded. Specifically, Defendants argue the American Academy of Professional Coders ("AAPC") has a required process for conducting retrospective reviews to determine the propriety of a medical provider's billing and coding for services, and that the process requires an audit of the relevant medical records to form an opinion on whether the

claims were properly coded or whether there has been overpayment. Defendants cite no legal authority for this proposition, instead relying exclusively on a 17-page printout from the AAPC website titled "Frequently Asked Questions on Medical Auditing," which describes procedures for how to conduct medical coding and medical billing audits as well as general important topics to remember when conducting or reviewing medical audits. (ECF No. 210-4). According to Defendants, these "established guidelines from the AAPC" are the only way to properly determine overpayment or damages, and because Ms. Endicott and Dr. King admitted to not conducting an audit or reviewing medical or billing records before opining on the propriety of Defendants' coding, their opinions lack the accepted scientific methodology to pass Rule 702 muster. Defendants also briefly, and without further analysis or support of legal authority, assert that because Ms. Endicott failed to conduct a full medical records audit, she cannot serve as a rebuttal witness to Defendants' expert Cristine Miller because she did not conduct the same kind of review.

The Government responds by clarifying the scope of the opinions their coding experts were asked to provide: Ms. Endicott and Dr. King were asked to give testimony regarding the correct CPT Code that defendants should have used to bill for the single urine drug test kit Defendants' used over the two year period between 2011–2013. There is no question that Defendants used the same urine drug test kit, with the same manufacturer's instructions, for every allegedly false claim at issue, and there is no question that Defendants coded the test as CPT Code 80101 for every claim at issue. Thus, the Government believes—and its experts testified that—no medical records review was necessary "because the medical coding analysis only involved determining the correct CPT code to bill when testing using one urine drug test kit." (ECF No. 212, at 14). The Government asserts that the coding experts' opinions are reliable because they consulted the CPT codebook and CPT Assistant (the undisputed authorities on interpreting the language of CPT codes) as well

as the manufacturer instructions in the test kit, and, using their personal experiences and knowledge of chemistry and medical coding, ultimately came to the conclusions that (1) the test kit used was a multiplexed screening kit, (2) the test was an immunoassay and did not use a chromatographic method based on the package instructions, and (3) the correct billing code for this type of test is CPT Code 80104, not 80101.

Rather than responding to the Government's clarification as to the actual scope of the experts' opinions and reports, Defendants doubled down on their argument that these experts and their opinions should be excluded for failure to follow the AAPC guidelines. Ultimately, Defendants maintain that a coding and medical records audit is required for the experts to render any opinions as to the proper coding here, and that both experts' opinions on coding should be excluded. Defendants also revived their assertion that Ms. Endicott cannot serve as a rebuttal witness to Ms. Miller because she did not conduct the same level of review by failing to conduct a full audit, meaning Ms. Endicott did not rebut evidence "on the same subject matter" as Ms. Miller's report. *See* ECF No. 218 (quoting *City of Gary v. Shafer*, No. 2:07-cv-56, 2009 WL 1370997, at *3 (N.D. Ind. May 13, 2009)).

"For an expert opinion to have a proper foundation, there must be a 'link between the facts or data the expert has worked with and the conclusion the expert's testimony is intended to support.'" *Bezingue v. Steuben Lakes Reg. Waste Dist.,* 507 F. Supp. 3d 1021, 1030 (N.D. Ind. 2020) (quoting *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2003)). Ultimately, "[t]he role of the judge is to ensure that the testimony the jury hears satisfies Rule 702's reliability requirements: that the expert is using a valid methodology (scientific or otherwise), that there is sufficient data to justify the use of the methodology in the particular case, and that the expert applied the methodology appropriately." *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th

Cir. 2013) (citing Fed. R. Evid. 702(b)-(d)). The question of reliability under Rule 702 "is primarily a question of the validity of the methodology employed by an expert, not the quality of the data used in applying the methodology or the conclusions produced." *Manpower, Inc. v. Ins. Co. of Pa.,* 732 F.3d 796, 806 (7th Cir. 2013). To pass Rule 702 scrutiny, there need only be a "rational connection between the data and the opinions." *Id.* at 809.

The Court finds a rational connection existed here between the data and the opinions provided by both Ms. Endicott and Dr. King as to the proper coding of this type of urine drug test. Both Ms. Endicott and Dr. King thoroughly reviewed the materials provided—the AMA's CPT codebook and CPT Assistant, relevant Indiana Health Coverage Programs Provider Bulletins, and the package materials from the Wondfo test kit—and, using their own experiences with medical coding combined with their review of the materials, rendered high level opinions as to how this particular test kit should have been coded. All parties agree that the AMA's CPT guidance from the codebook and the CPT Assistant is authoritative on analyzing a CPT code. *See* ECF No. 183-3, Deposition of C. Miller at 92:5–8. The two experts admittedly relied on the Government's assertions that the same test kit was used for every claim, and that every claim was coded as 80101. But relying on those assertions does not render their expert opinion inadmissible or unreliable. Ultimately, the materials reviewed combined with the experts' own experience and knowledge allow both Ms. Endicott and Dr. King to give an opinion on which CPT code is proper for the Wondfo drug screening test kit used by Defendants.

This is not the first time Defendants have banged the proverbial drum over the AAPC guidance, nor will it likely be the last. As in their briefing at the summary judgment stage, Defendants once again fail to provide any citation to legal authority in support of their assertion that a medical records audit is required for a coding expert to opine on the propriety of a provider's

coding.[1] But even if the Court found that the AAPC guidelines outlined the proper methodology for rendering an opinion identifying overpayments or the propriety of coding for individual claims, Defendants simply fail to acknowledge that those opinions were *not* rendered by Ms. Endicott or Dr. King, nor do they make any argument as to how the methodology the experts *did* apply to the opinions they *did* render—that the specific test kit used by Defendants should be coded as CPT code 80104, not 80101—was somehow insufficient or unreliable.

Though the Court could find few cases with similar circumstances, one case out of the Middle District of Florida is instructive. In *Taylor v. Allworth*, No. 8:19-cv-1761, 2021 WL 4311051 (M.D. Fla. Sept. 22, 2021), the defendants asked the court to completely exclude the plaintiff's coding expert—a Certified Professional Coder—because she failed to conduct a medical records or billing "coding analysis" in rendering her opinion. Rather than exclude her entirely, the court found the expert could testify on a limited, high-level basis based on the scope of her review. *Id.* at *5. Our case differs, however, because the expert in *Taylor* was attempting to opine on medical reasonableness which *would* require an auditing-style review of medical records; the Government's experts here make no such assertions and have always limited the scope of their opinions to the high-level issue of how to properly code this type of drug screening test kit. As in *Taylor*, Defendants' argument that the Government's experts "rendered no opinions as to the propriety of how the Defendants actually billed for their urine drug testing services, nor did they identify any overpayments or damages as would be required for an FCA case" (ECF No. 218, at 6) may have highlighted faults in the Government's litigation strategy, but as to the experts they

[1] As noted in this Court's Opinion and Order on summary judgment, "the Defendants do not explain why a review of medical records is necessary for establishing damages based on the Government's theory of the Defendants' liability in this case, which stems from the type of drug screen kits the Defendants used and their improper use of the corresponding CPT Code and Modifier 91." ECF No. 184, at 17 n.7.

"have merely raised deficiencies in [the experts'] knowledge and preparation that they may pursue on cross examination." *Taylor*, 2021 WL 4311051, at *5. Ultimately, the fact that Defendants and their experts disagree with the Government's experts' conclusions is not the proper focus of a *Daubert* motion but instead is an issue to be explored in cross examination and decided by the jury. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment.").

Finally, as to Ms. Endicott's propriety to serve as a rebuttal witness to Defendants' expert Cristine Miller, even if this argument were not waived for failure to provide analysis or legal authority in their opening brief, *see White*, 8 F.4th at 552, the Court finds this assertion meritless. A review of Ms. Endicott's report shows her report was limited to rebutting Ms. Miller's opinions on the proper coding of the Wondfo test kit. Indeed, Ms. Endicott wisely refused to respond to portions of Ms. Miller's report which would require a review of the medical or billing records. *See* ECF No. 218-1, at 11 (noting that Miller's opinion on a random sample of the claims "is outside the scope of this Medical Coding Report"). Unlike the cases cited as support by the Defendants, then, Ms. Endicott's report does indeed rebut Ms. Miller's opinion on the narrow issue of the proper coding for the test kit, meaning she has provided a proper rebuttal opinion.

Thus, the Court finds the Government's coding experts applied reliable methodology. As such, Ms. Endicott and Dr. King will not be excluded from testifying about proper CPT coding,[2]

[2] Defendants did not assert a challenge for the third step of a *Daubert* analysis—whether the testimony will assist the trier of fact with its analysis of any of the issues involved in the case, *see Smith*, 215 F.3d at 718—but the Court would have no trouble finding that Dr. King's and Ms. Endicott's proposed testimony regarding coding will assist the jury here. Proper CPT coding is not something that is obvious to a layperson or a matter that is "within the average juror's comprehension." *Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998). Having a Certified Professional Coder

and the Court denies Defendants' Motion to Exclude Testimony Regarding Coding. (ECF No. 210).

B. Chromatography Experts

Three of the Government's expert witnesses—Ms. Endicott, Dr. King, and Dr. Ann Zerr—have provided testimony regarding the chemical testing methodology of the urine drug screening tests, specifically opining that the tests did not use a chromatographic method as defined by the AMA or otherwise.

By way of background, chromatography "is the collective term for a set of laboratory techniques for the separation of mixtures." *Trivitis, Inc. v. Ocean Spray Cranberries, Inc.*, 2012 WL 1944827, at *4 (S.D. Cal. May 29, 2012); *see also Chromatography*, Merriam-Webster, https://www.merriam-webster.com/dictionary/chromatography (defining "chromatography" as "a process in which a chemical mixture carried by a liquid or gas is separated into components as a result of differential distribution of the solutes as they flow around or over a stationary liquid or solid phase").

These three experts have varying levels of experience and training in chemistry. Ms. Endicott took some chemistry classes in college. (ECF No. 223-2, at 30). Dr. Zerr was also exposed to the study of chemistry in both her undergraduate and medical school classes and further testified that every physician's training included a "robust science background" which included the understanding of concepts and methods such as chromatography. (ECF No. 223-3, at 65, 92). Dr. King's chemistry experience is the most profound of all: beyond the chemistry education he received as a training and then practicing physician, he received a Bachelor of Arts in Chemistry and has authored or co-authored multiple published papers in the fields of chemistry and

and a practicing physician responsible for coding his services will certainly help the jury understand the factual issues in this case.

biophysics. (ECF No. 211-12). All three used their varied experiences as well as the AMA's CPT guidance in making their determinations that the Wondfo test kit used by Defendants did not use a chromatographic method, meaning the tests should have properly been coded as CPT Code 80104, not 80101.

The main thrust of Defendants' *Daubert* motion is that the testimony of these three experts concerning chromatography is beyond the scope of their expertise and should thus not be permitted at trial. For the medical doctors, Defendants argue the doctors' only qualifications are their experience and training as physicians and that "[h]aving a science background in medicine . . . does not equate to chemical engineering, which would be required to opine as to the issue of chromatography." (ECF No. 211, at 21–22). As to Ms. Endicott, Defendants point to her lack of chemistry training as well as her testimony admitting that she is "not holding [herself] out as an expert in testing methodologies." (*Id.* at 24). Defendants also make an additional argument that the basis of the Government's experts' opinions is unreliable because they rely exclusively on the definitions and language provided by the AMA in its CPT materials, which the Defendants asserts "is not *prescriptive*" but is instead "*descriptive*," meaning "it does not, and indeed it cannot, dictate what the testing methodology was that the Defendants' test kits utilized." (ECF No. 211, at 18). The Court understands this assertion to be a challenge to the experts' methodology, rather than their qualifications.

In response, the Government argues their experts are qualified—Drs. King and Zerr based on their medical doctor training, which included required chemistry coursework; Ms. Endicott based on her coding qualifications and experience—to render their opinions that the Wondfo test kit utilized a non-chromatographic testing method and thus should not have been coded as CPT Code 80101. The Government also counters Defendants' reliability argument by pointing out the

unreliability of the opinions of Defendants' own chromatography experts' opinions,[3] then once again relies on *Smith v. Ford Motor Co.*, 215 F.3d 713 (7th Cir. 2000), as support for allowing these three experts to testify, considering their education and experience despite not being trained chemical engineers.[4] Finally, the Government contends its experts' testimony will help the jury "understand, and distinguish, the difference between the chromatographic absorbent device that defendants used for urine drug tests that they billed to Indiana Medicaid and a chromatographic method" as defined by the AMA in its CPT materials. (ECF No. 214, at 22).

In their Reply, Defendants re-asserted the importance of chromatography as a central issue in this case and disclaimed the Government's reliance on the AMA's CPT guidance as the "authoritative" definition of chromatography. The Defendants' Reply once again touts the lack of qualifications of the Government's experts, in particular noting that the medical experts—Drs. King and Zerr—should be excluded because they were asked "to provide opinions as to what [they] think[ ] the Defendants *objectively* should have known regarding how urine drug tests are billed,"

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[3] While the Government argues that the testimony of Defendants' experts—Dr. Brittany Givens and Kunyan Mao—is unreliable and lacks credible factual basis, it has not filed its own *Daubert* motion to exclude the testimony of these experts. As such, the Court will interpret this portion of the Government's argument as a counterexample to showcase the relative reliability of its own experts and will not further address these assertions here.

[4] The Government also points out Defendants' use of misleading or selective quotations in its briefing, most concerning being the Defendants quoting the test kit materials as declaring "It is chromatographic." (ECF No. 211, at 5). From Defendants' own exhibit, the full quoted language from the test kit materials provides: "One Step Multi-Drug Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. *It is chromatographic absorbent device* in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites." (ECF No. 211-5, at 1 (emphasis added)). Though this is not relevant to the current *Daubert* inquiry, the Court is nevertheless troubled by this misleading tactic and notes that this is not the first time Defendants have misrepresented the test kit language in this way. *See* ECF No. 170, at 4 ("First, the literature provided with the test kits and even the test boxes themselves state that the test 'is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. *It is chromatographic*.'" (emphasis in original)); ECF No. 241, at 11 ("Dr. Givens' testimony is supported by statements from the manufacturer of the test kits, as well as the language of the literature and instructions affixed to the test kits, themselves, all of which identify the test kits as immunoassays which 'are chromatographic.'"). The parties are reminded of their duty of candor to the Court and that "[m]isleading statements are unacceptable and run afoul of Federal Rule of Civil Procedure 11(b)." *Eckhardt v. State Farm Bank FSB*, 2019 WL 1177954, at *6 (C.D. Ill. March 13, 2019). Counsel should endeavor to ensure all future filings comply with Rule 11 and are free from misleading or inaccurate statements.

which they assert "is inconsequential to establishing the FCA's scienter requirements, and would only serve to confuse the issues in this case." (ECF No. 219, at 14).[5]

The Court will address the experts' qualifications first before turning to the Defendants' claim that the AMA CPT materials are "descriptive" rather than "prescriptive," which the Court understands as a challenge to the reliability of the experts' methodology in forming their opinions.

i. All three Government experts are qualified to testify about chromatography, to some extent

Defendants contend none of the Government's three experts are qualified to testify about chromatography—and thus whether the Wondfo test kits used a chromatographic testing method—because they are not sufficiently trained in chemistry nor do they work as chemical engineers.

In response, the Government highlights the chemistry coursework and additional chemistry training and experience completed by practicing physicians Drs. King and Zerr, and notes that Ms. Endicott's extensive coding experience, in which she has performed many coding analyses for clients, render her qualified "to review the urine drug test kit actually used by the defendants, the language in the CPT Code Book related to CPT Codes 80101 and CPT Code 80104, and determine[ ] which CPT Code defendants should have billed to Indiana Medicaid." (ECF No. 214, at 11). From the Court's understanding, then, the Government essentially argues their experts' testimony on chromatography was sufficiently limited to their actual expertise: the doctors opined

[5] As with Defendants' scienter argument made in their motion regarding the coding experts, Defendants once again have provided no legal authority to support its assertion that the doctors' testimony on how a doctor objectively should have known to code the tests is "inconsequential" to the FCA's scienter requirements and would "confuse" the issues here to the point where it must be excluded altogether. While it may be true that liability for an FCA claim requires establishing subjective rather than objective knowledge, *see United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023), that means that the experts' opinions on how an objectively reasonable doctor would act cannot alone support a finding of liability. That said, such testimony is likely important information for a jury to have when deciding whether Defendants had the required subjective knowledge. Because this argument, like its previous iteration in the Coding Expert motion, is unsupported by authority, the Court will not address it further.

on chromatography as would be understood by a practicing physician such as Dr. Wagoner; the coding expert opined on the AMA definition of chromatography and how she, as a coding expert, would understand the Wondfo test kit to have correctly been coded. The Court agrees with the Government that these experts are qualified to testify about chromatography in the limited extent they opined in their expert opinions and depositions.

From the outset, it is clear from Dr. King's extensive training and experience in chemistry (as outlined above) that he is qualified to testify generally about chromatography—including providing a background explanation on the mechanics of chromatography—in order to render his opinion that the Wondfo test kit is not chromatographic based on his chemistry expertise combined with his review of the AMA's CPT materials. Though Defendants argue that Dr. King's chemistry education is too outdated for him to be considered an expert here or that he has pointed to no particular continuing medical education specifically about chromatography, those claims once again go to the weight of his opinion, not its admissibility. *See Anderson v. Raymond Corp.*, 61 F.4th 505, 509 (7th Cir. 2023) ("Ordinarily, courts impose no requirement that an expert be a specialist in a given field.") As a reminder, "[t]he question . . . is not whether an expert witness is qualified in general, but whether his qualifications provide a foundation for him to answer a specific question." *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010). Here, Dr. King's education and experience provide a foundation for him to explain what chromatography is and answer whether the test kit uses a chromatographic method.

As to Dr. Zerr and Ms. Endicott, who openly admitted to their somewhat limited understanding of chemistry and chromatography, a more nuanced approach must be taken. Like the Seventh Circuit in *Gayton*, "we must look at each of the conclusions [the expert] draws individually to see if [s]he has the adequate education, skill, and training to reach them." *Id.* For

both Dr. Zerr and Ms. Endicott, the Court finds they are qualified to testify in a limited capacity as to chromatography and whether the Wondfo test kit utilizes a chromatographic method.

Between Dr. Zerr's responses to the request for interrogatories and her deposition testimony, she essentially made three conclusions after adopting "chromatography" as defined in the CPT materials: (1) she believes chromatographic testing requires expensive equipment; (2) based on a review of the test kit and AMA's CPT materials, the test kit does not use a chromatographic method; and (3) the appropriate CPT code to use for a multiplexed screening kit is CPT Code 80104, not 80101. The Court finds that she was qualified to render each of these conclusions. Dr. Zerr has been a practicing physician since receiving her MD in 1985. She testified multiple times that a physician's training includes chemistry topics that would cover testing methods such as chromatography, and that her understanding of chromatography was formed from that training as well as her review of the materials here.[6] Her testimony included a discussion of the difference between a more complex chromatographic test as opposed to a simpler testing method such as a urine drug or pregnancy test, *see* ECF 223-3, at 67, but notably her testimony did not dive into a higher-level chemistry discussion such as that in Dr. King's report and testimony. Instead, Dr. Zerr's testimony was appropriately cabined to that which she knew from her training and experience as a doctor. As with the Defendants' attempt to discredit Dr. King's coding experience because of his lack of specific certifications, the fact that Dr. Zerr—or any of these experts—is not a chemist or a chemical engineer does not mean she cannot testify as to her understanding based on her education and experience as a physician. Again, "[t]he question . . . is not whether an expert witness is qualified in general, but whether his qualifications provide a

[6] Notably, Dr. King also testified that his medical education and continued medical practice has included understanding chemistry and testing methodology topics such as chromatography. *See* ECF No. 223-2, at 142.

foundation for him to answer a specific question." *Gayton*, 593 F.3d at 617. Also as discussed above, what an ordinary practicing physician would know about a complex topic like chromatography is important to understanding how an ordinary physician might comprehend the test kit and CPT materials to arrive at the correct CPT code. Defendants' focus on Dr. Zerr's inconsistent testimony—such as her somewhat conflicting opinions on qualitative as opposed to quantitative chromatography, *see* ECF No. 223-3, at 87—or any other discrepancies in her conclusions are points to be explored in cross-examination, not a reason to exclude her testimony altogether. *See Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010) (holding that where a party's challenges to the proposed expert testimony "do not go to admissibility but to the appropriate weight that should be accorded to the evidence[,] '[d]etermination on admissibility should not supplant the adversarial process; shaky expert testimony may be admissible, assailable by its opponents through cross-examination.'" (quoting *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir.2010)).

As for Ms. Endicott, the only relevant conclusion about chromatography she makes is her agreement with Dr. King that the Wondfo test kit "is not a chromatographic method of testing for drugs in the urine but is instead an immunoassay method." (ECF No. 218-1, at 3). Her report explicitly notes that she bases her opinion on the AMA's definitions as provided in the CPT materials, specifically the definitions for "chromatography" and "immunoassay" as defined in the CPT Assistant Fall 1993. (*Id.* at 5). Despite defense counsel's badgering during her deposition, *see, e.g.*, ECF No. 223-2, at 70, 100, Ms. Endicott consistently limited her explanation of chromatography and her opinion that the test kit was not chromatographic as being based *solely* on the CPT guidance provided by the AMA. Critically, she offered no expert opinion about chromatography generally, just provided her understanding of the AMA's definitions and how

those apply to the different CPT codes. As a Certified Professional Coder, she is well qualified to testify about the AMA definitions in the CPT materials and how those would translate to coding a particular test such as the Wondfo test kit. And as with Dr. Zerr, should Ms. Endicott's trial testimony stray into the realm of testifying generally about more complex chromatography topics, that testimony would likely be outside the scope of her expertise—but at this stage there is no indication that Ms. Endicott has or intends to speak beyond her CPT and coding knowledge.

Ultimately, the Court finds Dr. King is eminently qualified to opine on chromatography generally, and Dr. Zerr and Ms. Endicott are qualified to render their cabined opinions on chromatography and whether the Wondfo test kit utilized a chromatographic method based on their own experience and training.

ii. The Government's chromatography experts' methodology is sufficiently reliable

Defendants spill much ink arguing that these experts' opinions on chromatography should be excluded because they rely almost exclusively on the AMA's definition of "chromatography" as defined and expounded upon in the CPT materials.[7] Specifically, Defendants claim that the language of the CPT materials is "prescriptive" as opposed to "descriptive" because "it does not, and indeed it cannot, dictate what the testing methodology was that the Defendant's test kits utilized." (ECF No. 211, at 18). They assert that the CPT Assistant "is not a recognized scientific journal and is not intended to be used as a basis for determining something such as the chemical methodology by which a drug test is administered." (*Id.*). In response, the Government asserts that

[7] Based on Ms. Endicott's expert report which provides the most in-depth recitation of the CPT materials, the CPT Assistant Fall 1993 and CPT 2011 Professional Edition provide the following guidance: "Chromatography (absorption analysis) is defined as the separation of chemical substances by differential absorption into a moving, two-phase system. In gas-liquid chromatography, gaseous substances are separated by movement through a liquid phase. If one did not have this resource readily available, CPT content in guidelines preceding code descriptor for 80100 describe chromatography as a two phase process: 'For chromatography, each combination of stationary and mobile phase is to be counted as one procedure.'" (ECF No. 218-1 at 5).

the AMA CPT guidance and definitions of "chromatography" and a chromatographic method—as opposed to a theoretical understanding of chromatography as provided by the Defendants' expert Dr. Givens—is in fact authoritative when attempting to determine the correct CPT code that the defendants used when billing Indiana Medicaid. (ECF No. 214 at 16, 18).

The Court understands Defendants' arguments as pointing toward the reliability of the experts' underlying data and subsequent methodology, but the Court agrees with the Government that their experts' methodology is sufficiently reliable to support the opinions rendered. The Seventh Circuit generally has held that "[r]eliability . . . is primarily a question of the validity of the methodology employed by an expert, not the quality of the data used in applying the methodology or the conclusions produced." *Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013); *see also Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment.").

The Seventh Circuit recently brought *Manpower* and its separation of methodology from underlying data into question in its freshest *Daubert* opinion, noting the 2023 amendments to Rule 702 altered its reliability subsection to clarify that "questions of the sufficiency of an expert's basis" go to admissibility just as with questions of "the application of the expert's methodology." *Gilbert v. Lands' End, Inc.*, 2025 WL 2982190, at *5 n.3 (7th Cir. Oct. 23, 2025). The note in *Gilbert* seems to imply that *Manpower*'s strict formulation of the standard—i.e., firmly distinguishing between reliable methodology and "the quality of an expert's data and conclusions"—may no longer be appropriate after the 2023 amendments. That said, just as the Seventh Circuit held in *Gilbert*, the conclusion in this case would be the same under either standard

because, objectively, using the CPT materials (which experts on both sides agree are authoritative for deciding correct coding) to determine the correct CPT code is a sufficient basis to support the experts' opinions. With the 2023 amendments to Rule 702, the Advisory Committee notes that "if the court finds it more likely than not that an expert has a sufficient basis to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility." Fed. R. Evid. 702 Advisory Committee's Note to 2023 Amendment. Additionally, where experts come to different conclusions based on "contested sets of facts," the Committee explains that such a situation "does not necessarily require exclusion of either side's experts" but instead "by deciding the disputed facts, the jury can decide which side's expert to credit." *Id.*

Just such a situation has evolved here. Without citation to legal authority, Defendants confusingly claim the CPT materials' "prescriptive" rather than "descriptive" nature means it is unreliable, and their only evidence to support that unreliability are the opinions of their own witnesses who come to different conclusions about the testing methodology of the Wondfo test kits. But as noted above, differing expert conclusions alone do not render one side's expert's opinions inadmissible, and Defendants simply have provided no persuasive reason for why the AMA's CPT definitions should be considered unreliable. They have pointed to no opinions indicating the CPT materials and definitions are false or incorrect. Indeed, the Defendants' own expert testified that the CPT materials—including its definition of something like "chromatography"—are definitive when determining how to properly code for billing purposes. *See* ECF No. 183-3, Deposition of C. Miller at 92:5–8. Thus, the Court is unpersuaded by the Defendants' assertions and agrees with the Government that the definitions and instructive language furnished by the AMA in its CPT materials provides a sufficient basis to support the

experts' conclusions that the test kit would not be considered a "chromatographic method" as understood by the AMA, further supporting the shared opinion that CPT Code 80104 was the proper billing code.

At the end of the day, almost all of Defendants' arguments boil down to this simple assertion: the Government's experts' opinions are inadmissible because they are wrong. It's possible that may be true, and Defendants provide their own expert opinions to support that assertion. Nevertheless, the Court's *Daubert* gatekeeping function is not reserved for it to determine which parties' expert is more right—that debate should take place in cross examination, where both sides can test the weight of their evidence in front of the jury. *See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 2011 WL 6302287, at *3 (S.D. Ill. Dec. 16, 2011) ("Resolution of an expert's credibility or the correctness of his or her theories under the particular circumstances of a given case is a factual inquiry, left to the jury's determination after opposing counsel has cross-examined the expert at issue as to the conclusions and facts underlying his or her opinion."). To the extent the Defendants disagree with the Government's experts' conclusions or that certain portions of their testimony may be less credible, the appropriate method for challenging such testimony is through cross-examination, not exclusion. *See Daubert*, 509 U.S. at 596.

With the above in mind, the Court finds the Government's experts applied reliable methodology when coming to their conclusions about chromatography and whether the test kit used a chromatographic method. As such, Dr. King, Dr. Zerr, and Ms. Endicott will not be excluded from testifying about chromatography (to the limited extents as outlined above),[8] and the

[8] As with the first *Daubert* motion, Defendants did not assert a challenge for the third step of a Rule 702 analysis: whether the testimony will assist the trier of fact with its analysis of any of the issues involved in the case, *see Smith*, 215 F.3d at 718. And once again, the Court would have no trouble finding that the three experts' testimony regarding

Court denies Defendants' Motion to Exclude Testimony Regarding Chromatography. (ECF No. 211).

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude Testimony Regarding Coding (ECF No. 210) as well as their Motion to Exclude Testimony Regarding Chromatography (ECF No. 211) are both DENIED.

SO ORDERED on December 4, 2025.

s/ Holly A. Brady
CHIEF JUDGE HOLLY A. BRADY
UNITED STATES DISTRICT COURT

chromatography would assist the jury in this case as it is clearly not something obvious to a layperson or within the average juror's comprehension. *See Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998).